

### **Remarks**

This Amendment is in response to the Office Action dated **January 12, 2009**. The Office Action objected to the Specification, asserting, in part, that “Applicant has invoked ... means-plus-function language” thereby requiring Applicant to Amend the Specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o); objected to claim 3 asserting, in part, that “Applicant has evoked sixth paragraph, means-plus-function language...”; rejected claim 1 under 35 USC § 112, first paragraph; rejected claims 1 and 3 under 35 USC § 102(b) over Pshenichny et al. (US Pat. No. 3,750,667) (hereinafter “Pshenichny”); rejected claims 13-14 under 35 USC § 103(a) over Pshenichny; rejected claim 17 under 35 USC § 103(a) over Pshenichny in view of Mickley (WO 02/11807); and noted that claim 4 would be allowable if rewritten in independent form.

Claim 3 is canceled without prejudice or disclaimer. Claims 1 and 4 are herein amended. Support for this amendment can be found at least in the Specification in paragraph [0040] and in Figure 3. Applicants request reconsideration in light of the foregoing amendments and following comments.

### **Specification**

The Office Action objected to the disclosure for informalities, stating:

It is the Examiner’s position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant’s invention. Therefore, the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01 (o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element, what structure, materials, and acts perform the function recited in the certain element.

In making this objection, the Examiner refers to means language used in claims 3 and 4. Claim 3 is canceled and claim 4 is amended to eliminate any means language. In light of these amendments, Applicant submits that the requirements of MPEP 608.01(o) and 37 CFR 1.75(d) are satisfied. Therefore, Applicants request withdrawal of the objection to the Specification.

### **Claim Objections**

The Office Action objected to claim 3 “for the reasons set forth above in the objection to the specification.” In light of the cancellation of claim 3 and discussion above, Applicants request withdrawal of the objection.

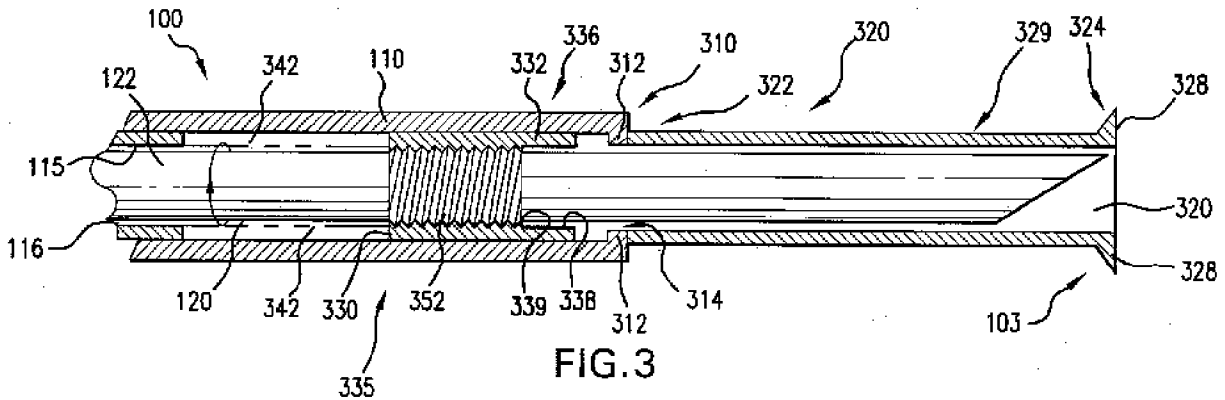
### **Claim Rejections – Section 112**

The Office Action rejected claim 1 under 35 USC § 112, first paragraph, alleging that the “claim(s) contain subject matter which was not disclosed in the specification...” The Office Action further alleges, “no where in the specification discloses the limitation that ‘rotation of the needle within the first elongated shaft causes longitudinal movement of the stop collar relative to the needle within the first elongated shaft’.” This rejection is *traversed*.

Applicant asserts that a person of ordinary skill in the art would recognize that by rotating a threaded inner member within a corresponding threaded outer member, the threaded outer member moves longitudinally relative to the inner member. This concept is an inherent product of threads.

As stated in section 2163.07(a) of the MPEP, “[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it.”

In this case, as the threaded needle 120 is rotated within the stop collar having inner threads 339, the stop collar moves longitudinally relative to the needle much like a nut moves longitudinally relative to a bolt when the bolt is rotated and the nut is prevented from rotating.



Considering relative longitudinal movement is an inherent property associated with threading an inner member inside of a rotationally fixed outer member as shown in Figure 3, Applicants request withdrawal of the rejection.

#### Claim Rejections – Section 102

The Office Action rejected claims 1 and 3 under 35 USC § 102(b) over Pshenichny. Without forming an opinion as to the validity of this rejection, claim 1 is amended in furtherance of prosecution.

Claim 1 recites, in part “a stop collar disposed within the first lumen of the first elongated shaft near the distal end of the needle; the stop collar having a portion thereon configured to prevent lateral movement of the stop collar within the first elongated shaft...” Support for this amendment can be found at least in the Specification at paragraph [0040] and in Figure 3.

The Office Action asserts that Pshenichny discloses:

a stop collar [that] is a portion formed of a second set of male thread 2 corporate [sic cooperate?] with a first set male thread of inside tube needle 7 (Figs. 1-2 or see Fig. 2 below is enlarged); wherein rotation of the needle within the first elongated shaft can be caused longitudinal movement of the stop collar relative to the needle within the first elongated shaft because the threading motion step of two thread surface engaged with each other, the positioning of the stop collar/female thread section located within the first elongated shaft controlling a variable extent to which the needle may be extended beyond the distal end of the first elongated shaft...

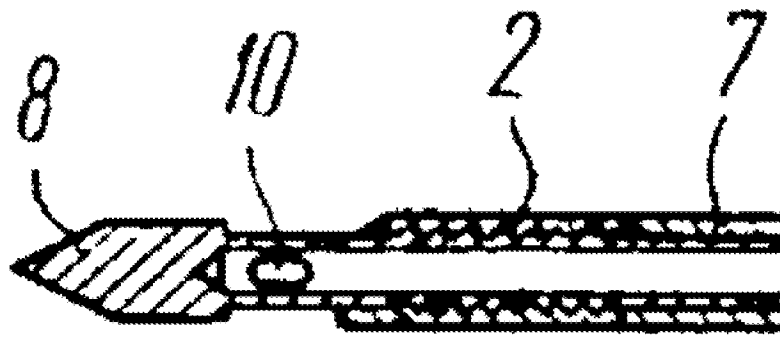


FIG. 2

Pshenichny discloses a “device for intraosseous injection of liquid substances.” See Figures 1 and 2, below. The device of Pshenichny “comprises an outside tube 1 having a male thread 2 on its effective (introducible) portion, and a head 3.” Column 2, lines 8-10. The device further comprises “a hollow inside tube 7 (FIG.3) having a pointed tip 8 (FIGS. 1, 2),” as shown below. Column 2, lines 18-19. Additionally, the device comprises a “movable restrictor 12 to control the depth of introduction of the device into osseous tissue.” Column 2, lines 35-37.

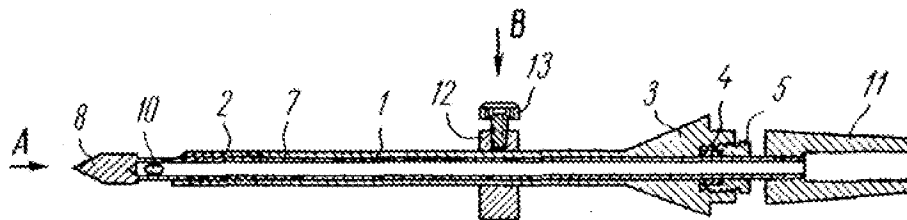
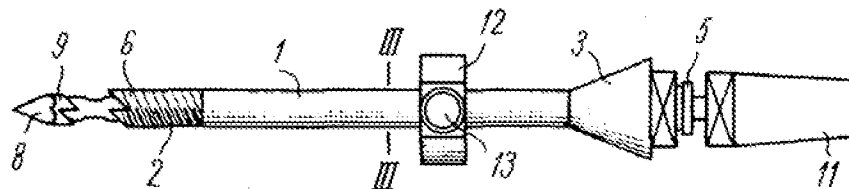


FIG. 2



Pshenichny at least fails to disclose a “stop collar” as is claimed in independent claim 1. The Office Action suggests “that a stop collar is a portion formed of a second set of male thread 2 corporate with a first set of male thread of inside tube/needle 7.” Applicants disagree.

Applicants disagree with the Office Action's assertion that Pshenichny teaches a "first set of male threads" that cooperates with a "second set of male thread[s]." However, even assuming, for the sake of argument only, that Pshenichny discloses such a device, Pshenichny does not satisfy the claimed limitations.

Claim 1 requires "a stop collar disposed within the first lumen of the first elongated shaft near the distal end of the needle; the stop collar having a portion thereon configured to prevent lateral movement of the stop collar within the first elongated shaft..." Nowhere does Pshenichny teach a stop collar, much less a stop collar having a portion thereon configured to prevent lateral movement of the stop collar within the first elongated shaft. Therefore, Applicants request withdrawal of the rejection.

### **Claim Rejections – Section 103**

The Office Action rejected claims 13-14 under 35 USC § 103(a) over Pshenichny. In making this rejection, the Office Action states, "Pshenichny discloses the claimed invention except for the shaft made of a low friction material such as polytetrafluorethylene." This rejection is *traversed*.

As discussed above, Pshenichny does not teach or suggest a "stop collar" as claimed in independent claim 1. Therefore, claims 13-14 are patentable over Pshenichny for at least the reasons discussed above.

The Office Action rejected claim 17 under 35 USC § 103(a) over Pshenichny in view of Mickley (WO 02/11807). Mickley does not remedy the deficiencies of Pshenichny, for example, as discussed in Applicants' Pre-Appeal Request for Review. Therefore, the subject matter of claim 17 is patentable over Pshenichny in view of Mickley and Applicants request withdrawal of the rejection.

**Conclusion**

For at least the reasons presented above, Applicants submit that the application is in condition for allowance. Favorable consideration and early action to that effect are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,

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